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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,168	09/10/1999	TOSHIMITSU ISHIKAWA	724-P10-2589	2333

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

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03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/393,168	ISHIKAWA ET AL.	
	Examiner	Art Unit	
	MINA HAGHIGHATIAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/29/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Remarks filed on 12/29/08. Claims **1-22** remain pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al (5,569,466) in view of Miskel et al (3,851,051).

Tanner et al teach **fill compositions for soft gel capsules** comprising an active agent dissolved or **suspended** in a carrier liquid (see abstract). Example 2 discloses a process of preparing a suspension wherein the **liquid** mixture is **homogenized** using high shear mixing techniques (see col. 4, lines 63-67). Examples 1, 2, 5, 6 and 8

disclose a fill composition comprising active agents and maltitol syrup (or lycasin) (a polysaccharide). No dispersion stabilizers, oil or fats are included. Examples 4 and 7 disclose fill compositions comprising active agents, maltitol syrup and peppermint oil. No dispersion stabilizers included. Tanner et al teach fill formulations comprising a polysaccharide such as lycasin, however does not specifically teach adding a dietary fiber.

Miskel et al teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited oil solubility (diphenhydramine) (see Example 1). Further, Miskel et al teach a soft capsule comprising a **water-soluble dietary fiber** (apple pectin), a material of limited oil soubility (glycerin) and a fat and oil material or oil soluble material (vitamin E) (see Example 50). In Example 43, Miskel et al teach a soft capsule comprising a **water-soluble dietary fiber** (citrus pectin) and a material of limited oil solubility (sodium saccharine). No dispersion stabilizer and fat and oil material or oil soluble material is present. High stability is disclosed (column 1, line 18-25).

Miskel et al provide a **stable soft gelatin capsule** having a water containing solution or **suspension** of an active ingredient **in the fill** (see col. 3, lines 41-44).

Miskel et al provide a soft gelatin capsule having a fill containing as high as a15-20% water solution of an active ingredient, yet which has a long life and does not exhibit the problems of softening, deterioration, or attack by substances normally deleterious to the gelatin shell (see col. 3, lines 53-58).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the soft capsule formulations of Tanner et al, to have looked in the art for other ingredients such as water-soluble dietary fibers for the fill composition, as disclosed in Miskel et al with a reasonable expectation of successfully preparing a stable homogenized fill composition for soft capsules. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and **the combination would have yielded predictable results** to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Applicant's arguments filed 12/29/08 have been fully considered but they are not persuasive. Applicant takes the position that Examiner has not satisfied the requirements for establishing a presumption of obviousness. Applicant argues that "The Examiner has failed to establish why one of ordinary skill in the art would have been motivated to combine the citrus pectin of Miskel et al., which the Examiner characterizes as a water soluble dietary fiber, with the fill composition of Tanner et al. reference". This is not persuasive because it has been shown that the combination of the two references of record would have lead one of ordinary skill in the art to the claimed invention. Tanner et al and Miskel et al both teach soft capsules and the liquid fill compositions. Tanner et al teach that the fill compositions may comprise active agents such as nutritional supplements, plant extracts, nutritional additives, laxatives, antacids, and

breath freshener formulations. Tanner does not specifically disclose fiber. Miskel et al teach soft capsules comprising formulations comprising active agents and formulations such as breath freshener formulations which comprises pectin, a dietary fiber (see formulation 43). Other formulations comprising pectin fiber are formulations 49 and 50.

It would have been obvious to one of ordinary skill in the art to have included the pectin (dietary fibers) of Miskel in the soft capsules of Tanner et al. Obviousness comes from either the references themselves or the knowledge available to one of ordinary skill in the art. Here, it has been shown that Tanner et al discloses the general formulations and one of ordinary skill in the art could have looked in the art for specific species, and as well, one of ordinary skill in the art knows that the soft capsules can contain almost any active agent. It is a general delivery vehicle.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

All claims remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616